

### **REMARKS**

After the foregoing amendment, claims 1-18, 21, 24-34 and 36-38 are active in the present application. Claims 39-60 have been previously cancelled as being drawn to a non-elected invention. By the present amendment, claim 1 has been amended to incorporate therein the subject matter of claim 35 which has been cancelled. No new matter has been added to the application as a result of the amendment of claim 1.

#### **Art Rejections**

1. Claims 1-12, 17, 18, 21, 24, 26-28, 30 and 35-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Lauks et al. patent in view of newly cited U.S. Patent No. 6,153,085 (Patko et al.). It is the position of the Examiner that the Lauks et al. patent discloses all of the limitations of the set forth system as described in the prior Office Action dated September 11, 2003 but does not explicitly set forth an indicia which is unique for each test cell and does not set forth a reader for the indicia. The Examiner states that the Patko et al. patent, at column 10 lines 48-56, teaches in an alternate electrochemical sensor that a barcode can be utilized for storing information about the electrochemical sensor and that each barcode should be unique for that electrochemical sensor. Thus, as suggested by the Examiner, the barcode of Patko et al. allows more information to be transmitted to the instrument than can be transmitted by the notches of Lauks et al., including calibration and quality control information and whether the sensor had been previously inserted into the instrument. The Examiner concludes that it would have obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Patko et al. for the system of Lauks “in order to transmit more information about the test cell to the instrument including whether the strip has been previously inserted into the sensor”. The Examiner supports his conclusion by stating that this teaching is particularly “relevant to the teaching of Lauks” because the Lauks patent is drawn to a sensor “that is meant to be utilized once and discarded”. In support of the last statement the Examiner points to the title and the last sentence in the abstract of the Lauks et al. patent. The Examiner further concludes that “preventing the reuse of the test strip would potentially prevent a false analysis of a patient’s blood”. For the reasons as set forth in detail below the applicants respectfully traverse this rejection as applied to claim 1, as amended.

### Present Invention

The present invention comprises a system for conducting a plurality of different medical diagnostic tests. The system includes a hand held portable self contained instrument and a series of disposable, single use test cells for receiving fluid to be diagnostically tested. Each of the test cells includes identification information including indicia which is indicative of a particular diagnostic test to be performed by the electronic instrument upon the fluid contained within the test cell. The indicia on a particular test cell are unique to that particular test cell so that no two test cells contain the same indicia. This feature is particularly important to the present invention as it precludes a test cell from ever being used twice. Each test cell is sized and shaped for engagement by the instrument. The instrument includes a reader for reading the indicia on the test cell prior to engagement of the test cell by the instrument. The diagnostic test to be performed is selected by the instrument based upon the identification information obtained from the indicia on the test cell.

The instrument of the present invention further includes a unique identification code which distinguishes the instrument from all other instruments. The unique identification code is used to provide positive identification on all test results obtained using the instrument. In the preferred embodiment as described at paragraph 041 of the application and as shown on Fig. 4B, the unique identification code is established by a unique identification tag circuit 522 which establishes a digital serial number for each particular instrument. By insertion of the unique identification code into all test results obtained using the instrument it is possible to positively identify which particular instrument generated the test results thereby enhancing the quality control of the instrument and its test results. The unique identification code feature has been added to claim 1 in order to more particularly point out and distinctly claim the present invention.

### Prior Art

The Lauks et al. patent discloses an instrument for performing a variety of electrochemical measurements on blood or other fluids drawn into a disposable device. The disposable device includes a series of notches (28, 30, 32 and 34) which are utilized by the instrument after the disposable device is inserted into the instrument to indicate the particular test to be performed on the blood or other fluid within the disposable collection device.

Significantly, the Lauks et al. patent contains no reader other than the reader which is utilized to decode the notch pattern on the device after the device has been inserted into the instrument. Thus, the Lauks et al. patent does not disclose the concept of indicia on the test cell or device nor does it disclose or suggest that the instrument include a reader for reading the indicia on the test cell prior to engagement of the test cell by the instrument as called for in claim 1 as amended.

The Lauks et al. notch system does not, in any way, permit the instrument to determine whether an inserted test cell had been previously used. Although, as noted by the Examiner, it is the intention of the Lauks et al. patent that once a test cell has been used it “can be” withdrawn from the reader and discarded (see at last line of abstract), it is abundantly clear that there is no recognition of any kind in the Lauks et al. patent that the reuse of a test cell be actually prevented. Thus, the fact that the test cell of the Lauks et al. patent “is meant to be utilized once” as noted by Examiner does not provide any teaching or even the remotest suggestion that there should or could be something in the Lauks et al. instrument or on the Lauks et al. test cell itself which would prevent the test cell from being reused. It is therefore respectfully submitted that there is no teaching or suggestion in the Lauks et al. patent with respect to the desirability of having a feature that prevents reuse of a test cell.

The Patko et al. patent discloses an electronic sensor device for determining the ion concentration in a sample used in the medical diagnostics industry. The Patko et al. device integrates inexpensive, disposable semiconductor based processors or other information storage devices with disposable, pre-calibrated ion selective electrodes. The device stores information concerning its date of manufacture (i.e. shelf-life) in order to permit the sensor, itself, to more accurately and reliably calibrate itself to perform the requisite measurements. Thus, when the sensor device is inserted into a sensor data reader certain calibration points are calculated based upon information stored within the sensor concerning the initial efficiency rate, the rate of decay and the date of manufacture of the ion-selective membrane within the sensor. The reader uses the stored data to determine precisely the present efficiency of the sensor device to provide for a much more accurate sensor reading.

Although the major thrust of the Patko et al. patent is the improvement of the efficiency and accuracy of the sensor as a result of storing detailed data in an electronic memory, the patent does suggest that the data could, instead, be stored in other ways including by using a barcode. As correctly noted by the Examiner, at column 10 beginning at line 50 the Patko et al. patent

discusses that in a barcode embodiment the barcode may contain other information such as a serial number unique to each sensor to prevent reuse of the sensor as a result of the unique serial number being read into the sensor data reader and stored in a memory in the reader.

The Rejection Under 35 USC § 103(a) is Not Supported

It is well settled that when making a rejection under 35 USC § 103, the Examiner has the burden of establishing a *prima facie* case of obviousness. MPEP § 2142. The Examiner can satisfy this burden only by showing an objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art would lead the individual to combine the relevant teachings of the references in the manner suggested by the Examiner. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); MPEP § 2143.01.

In the present rejection it is respectfully submitted that the Examiner has failed to identify any such objective teaching. In the Office Action the Examiner has attempted to provide such a teaching by referring to the abstract in the Lauks et al. patent stating that the sensor of the Lauks et al. patent “is meant to be utilized once and discarded”. While the applicants agree that it is the intention of Lauks et al. to discard each sensor after it has been used once, it is respectfully submitted that there is no teaching or suggestion of any kind in the Lauks et al. patent of any structure which would preclude or prevent a sensor from being used more than once. There is no unique serial number or other feature of the Lauks et al. test cells which would permit a determination by the Lauks et al. reader with respect to whether a test cell had been previously used. The only interface between the Lauks et al. test cell and its reader which in any way distinguishes one test cell from another is the series of notches (28, 30, 32 and 34) which are utilized to indicate to a Lauks et al. reader the ionic species to be analyzed. However, as is readily apparent from the Lauks et al. patent, every test cell designed to perform a specific test will, by definition, have the exact same notch pattern. Thus, the Lauks et al. reader has no basis of any kind to distinguish whether a test cell has been previously used. Not only does the Lauks et al. patent lack any disclosed basis for distinguishing whether or not a test cell has been previously used, it is respectfully submitted that the Lauks et al. patent is totally lacking in any suggestion or teaching regarding the desirability of precluding reuse of a test cell. The language referred to by the Examiner in the Office Action is clearly insufficient to provide the necessary

linking teaching as required by the M.P.E.P. and the relevant case law. Moreover, it is respectfully submitted that such a linking teaching is just not present in the Lauks et al. patent.

Likewise, the Examiner has cited no linking teaching in the Patko et al. patent which would in any way suggest that the storage of a unique serial number within a barcode on the Patko et al. test cell could or should in any way be adapted for use in a test cell of the type disclosed in the Lauks et al. patent. Not only has the Examiner not pointed to any specific linking teaching in the Patko et al. patent, it is respectfully submitted that no such linking teaching is present in the Patko et al. patent.

In view of the foregoing it is respectfully submitted that the Examiner has failed to meet the requirement of properly combining the Lauks et al. and Patko et al. patents. As a result, it is respectfully submitted that the rejection of claim 1 and all claims departing therefrom under 35 U.S.C. § 103(a) should be withdrawn.

#### Newly Claimed Feature

By the foregoing amendment the applicants have incorporated into claim 1 the subject matter of cancelled claim 35 relating to each instrument including a unique identification code to provide positive identification of all test results obtained using the instrument. In the Office Action claim 35 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Lauks et al. patent in view of the Patko et al. patent. In the paragraphs on pages 3-5 of the Office Action the Examiner makes no specific reference to cancelled claim 35. However, at the bottom of page 2 of the Office Action the Examiner refers to the rejection of September 11, 2003. In the rejection of September 11, 2003 claim 35 was rejected as being unpatentable over the Lauks et al. patent in view of the patent to Ozawa et al. Because it is unclear to the applicants the true basis for rejecting claim 35 in the present Office Action, the applicants will address what the applicants believe to be the basis for the rejection as it might be applied to claim 1, as amended.

In the Office Action of September 11, 2003 with respect to claim 35 the Examiner refers to the Ozawa et al. patent at column 4 lines 18-40. The applicants have carefully reviewed the Ozawa et al. patent and particularly column 4 lines 18-40 and have been unable to identify any teaching or suggestion regarding the use of the instrument including a unique identification code which is employed for providing positive identification of all test results obtained using the instrument. The applicants have carefully reviewed the Lauks et al. patent and the Patko et al.

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patent and have been unable to identify a disclosure, teaching or suggestion in either of these patents regarding the instrument including such a unique identification code. As a result, it is respectfully submitted that the structural features of now cancelled claim 35 which have been incorporated into claim 1 are not disclosed, taught or suggested by any of the three references of record or any combination thereof. It is therefore respectfully submitted that claim 1, as amended, distinguishes over the Lauks et al., Patko et al. and Ozawa et al. patents or any proper combination thereof.

Claims 2-12, 17, 18, 21, 24, 26-28, 30 and 36-38 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Lauks et al. and Patko et al. either alone or in combination with other references such as U.S. Patent No. 4,797,188 (Tomita), U.S. Patent No. 4,798,705 (Makubowicz et al.) and U.S. Patent No. 5,405,510 (Betts et al.). It is respectfully submitted that each of these claims, which depends directly or indirectly from claim 1, distinguishes patentably over the various combinations of references at least for the same reasons as discussed in detail above with respect to claim 1. It is therefore respectfully submitted that the rejection of these claims should also be withdrawn.

In view of the foregoing amendment and discussion it is respectfully submitted that claim 1 as well as dependant claims 2-12, 17, 18, 21, 24, 26-28, 30 and 36-38 are in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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